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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,316	04/07/2004	Syed F.A. Hossainy	50623.285	8511

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EXAMINER

LIN, JAMES

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,316	Applicant(s) HOSSAINY ET AL.	
	Examiner Jimmy Lin	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,7,11,12,14,17 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8-10,13,15,16,18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/3/04, 8/29/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 3, 6, 7, 11, 12, 14, 17, and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/21/2006.

Specification

2. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.**

3. The disclosure is objected to because of the following informalities: On page 2, lines 16 and 17, "delivery" has been misspelled. Therefore, "delivery" should be changed to "deliver".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 5, 8 – 10, 13, 15, 16, and 19 are rejected under 35 U.S.C. 102(e) as being anticipate by Kokish (6,544,223).

Kokish teaches a partially inflated balloon of a catheter (column 6, lines 56 – 61) and coating the outer surface of the balloon with a polymer solution and a second solution (column 7, lines 8 – 15).

Claim 5: The inflated state is maintained at the same level during the application of the solutions to the balloon (column 7, lines 8 – 15).

Claim 8: A polymer solution is sprayed onto the balloon of a catheter (column 7, lines 8 – 15).

Claims 9,13: The coating on the balloon is allowed to air dry (column 7, lines 23 – 28). Once the fluid carrier is removed from the balloon, a dry form of the substance would inherently be left on the outer surface of the balloon. The inflated state is maintained at the same level during the drying process.

Claim 10: The balloon is completely deflated to a flattened configuration prior to the removal of the fluid carrier (column 7, lines 34 – 40).

Claim 15: A polymer solution is used in coating the balloon (column 7, lines 8 – 15).

Claim 16: The polymer solution is sprayed with a nitrogen pressure of 103 kPa (column 7, lines 8 – 17).

Claim 19: The balloon is partially inflated prior to the application of the solutions (column 6, lines 56 – 61).

6. Claims 1, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al. (6,120,477).

Campbell teaches that a balloon catheter is a device that can be used in a patient's blood vessel. The balloon can be inflated by filling it with a fluid once the balloon catheter is inside the patient's blood vessel (column 1, lines 18 – 27). The inside of the balloon surface is coated with the fluid filling the balloon, and the outside is coated with the patient's blood.

Claim 5: The balloon catheter is expanded until the desired result is accomplished (column 1, lines 28 – 33). Before the balloon is deflated, there will be a period of time when the inflated state is maintained.

Claim 8: The inside of the balloon surface is coated with the fluid filling the balloon, and the outside is coated with the patient's blood (column 1, lines 18 – 27).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (6,120,477) as applied to claim 1 above, and further in view of Shannon (6,537,247).

Campbell teaches inflating a balloon catheter inside a patient's blood vessel, but does not teach explicitly an inflated state that is hyper-inflated or inflated greater than a range of an intended expanded configuration. However, Shannon teaches when a balloon does not deflate as desired, a practitioner may over inflate the balloon to intentionally rupture the balloon wall, causing immediate deflation of the balloon and enabling withdrawal of the balloon (column 8 line 66 – column 9 line 3). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to over inflate the balloon of Campbell when the balloon does not deflate as desired. One would be motivated to do so with the expectation of deflating the balloon and removing the balloon catheter from the patient's blood vessel.

4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kokish (6,544,223) as applied to claims 1 and 16 above, and further in view of Fukaya et al. (6,613,066).

Kokish teaches a method of applying a polymer solution onto a balloon catheter as discussed above, but does not explicitly teach that gas is blown at the balloon subsequent to the application of polymer solution. However, Fukaya teaches a method of applying a polymer solution onto the balloon of a catheter and blow-drying the balloon (column 27, lines 54 – 64). The process of blow-drying would inherently blow a gas (i.e., air) at the balloon. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to have blow-dried the balloon catheter of Kokish, especially since Kokish air-dries the balloon. One would have been motivated to do so in order to evaporate the solvent in a shorter time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902.


Art Unit: 1762

The examiner can normally be reached on Monday thru Thursday 8 - 5:30 and Friday 8 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

06/06/2006



TIMOTHY MEEKS
SUPERVISORY PATENT EXAMINER